

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  51D0950359	<b>(X3) Date Survey Completed</b>  12/01/2020
<b>Name of Provider or Supplier</b>  Thomas Health Hematology Oncology At Tmh	<b>Street Address, City, State</b>  401 Division Street Suite 100, South Charleston, WV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced, on site, recertification survey was conducted at THS Physician Partners Inc on December 1, 2020, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
<b>D5891</b>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory written policies and procedures (P&amp;P), quality assurance (QA) records, and an interview with the technical consultant (TC1), the laboratory failed to establish and follow a written P&amp;P for the QA monitoring and evaluation of the laboratory post analytic test systems, which includes assessing practices/issues related to the accuracy and completeness of the laboratory test reports and procedures for notification of abnormal or panic values. Findings: 1. A review of written P&amp;P identified a THPP Oncology "Quality Assurance" P&amp;P that stated "Post-analytical- If the physician requests any further testing, the tube of blood will and (sic) sent to the main hospital laboratory for testing. To ensure the consistent quality of patient results, several monitors are utilized. All CBC results are reviewed by the physician." 2. A review of 2019 and 2020 QA records identified the following QA processes being documented as performed by the laboratory: "SYSTEM MONITORS: QC DOC, CA DOC, TEMP DOC, PT SUBMISSION, PT TESTING REVIEW, SPECIMEN MISLABELED" The system monitors being evaluated and documented for QA encompass the general laboratory, pre-analytic, and analytic systems. No documentation of post analytic QA processes could be located. 3. During an interview</p>

with the TC1, on 12/1/20 at approximately 11:00 AM, TC1 agreed the laboratory was not documenting the QA process for the post analytic systems, including accuracy and completeness of procedures for notification of abnormal or panic values.